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Notice: Expedited Review of Health Product Submissions and Applications to address COVID-19

Date: March 18, 2020

Our file number: 20-104980-839

On March 18, 2020, the Minister of Health approved an [Interim Order](#) Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. The interim order will enable an expedited review of medical devices indicated to diagnose, treat, mitigate or prevent COVID-19, at no cost.

COVID-19 is a new disease not previously identified in humans. Currently there is no vaccine or therapeutic product for COVID-19 that is authorized to treat or prevent the disease. The outbreak of COVID-19 has resulted in a global review of therapies that could be used to treat or prevent the infection.

Prior to a product being available on the Canadian market, Health Canada reviews product information to confirm the requirements of the *Food and Drugs Act* (FDA) and its associated regulations are met. Based on the information provided, the Department assesses the risks and benefits of the product to ensure Canadians have access to products that are safe, effective and of quality.

In an effort to facilitate earlier access to a vaccine, or therapeutic product for COVID-19, the Department will expedite the review of any COVID-19 related health product submissions and applications. Doing this will ensure timely access to novel therapies without compromising the safety, efficacy and quality of products.

As there are no existing therapies or vaccines to effectively treat or prevent COVID 19, there is an urgent need to get novel therapies into clinical trials. This will allow research in Canada of these novel therapies and provide Canadians access to new investigational therapies aimed at preventing or treating COVID-19. Clinical trials ensure the gathering of information to support the safety and efficacy of the product while allowing access under controlled circumstances. When such trials have sufficient evidence to support full market authorization, Health Canada will work with sponsors to expedite the development and authorization of these products. When expediting the review of submissions and applications with the goal of enabling timely access to vaccines and therapeutic products, Health Canada will continue to ensure products are supported by sufficient evidence of safety, efficacy and quality to merit access to Canadians.

Until a vaccine or therapeutic product is available on the Canadian market, Health Canada's Special Access Programs for Drugs and Medical Devices are available to practitioners or healthcare professionals requiring access

to drugs that provide supportive treatments to the infection, or diagnostic devices to identify COVID-19 in patients.

Sponsors wishing to file a submission or application should contact the appropriate review bureau.

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